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Authorization of Entities - Seeking guidance and direction from CPM on the draft ISPM on Requirements for NPPOs if authorizing entities to perform phytosanitary actions (2014-002)

Agenda item 10.4

Prepared by the Small Working Group of the Standards Committee

- [1] According to the IPPC Style Guide, “authorize” is to give authority to a person or a body to do something. From a phytosanitary perspective, authorization of entities other than national plant protection organizations (NPPOs) to perform specific phytosanitary actions such as inspection, testing, surveillance and treatment is becoming increasingly common around the world.

Use of the concept of authorization in IPPC

- [2] Article IV of the IPPC lays down the responsibilities for NPPOs. Article V.2(a) of the IPPC provides for the possibility for NPPOs to authorize entities (non-NPPO) to perform specific phytosanitary actions on their behalf. The concept of authorization is referred to in several adopted International Standards for Phytosanitary Measures (ISPMs), such as ISPM 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*), ISPM 5 (*Glossary of phytosanitary terms*), ISPM 6 (*Surveillance*), ISPM 7 (*Phytosanitary certification system*), ISPM 12 (*Phytosanitary certificates*), ISPM 20 (*Guidelines for a phytosanitary import regulatory system*), ISPM 23 (*Guidelines for inspection*), ISPM 42 (*Requirements for the use of temperature treatments as phytosanitary measures*) and ISPM 43 (*Requirements for the use of fumigation as a phytosanitary measure*). NPPO functions are considered official. As per ISPM 5, official is defined as, “established, authorized or performed by a national plant protection organization”. The responsibility for NPPO functions and authorized activities would always remain with the NPPO. If an NPPO decides to authorize entities, it has sole responsibility for deciding which entity is authorized and for which specific phytosanitary actions. The NPPO is responsible for ensuring that the authorized entity performs the phytosanitary actions according to the NPPO’s requirements. However, NPPO functions such as issuance of phytosanitary certificates, and development and establishment of phytosanitary measures cannot be delegated to authorized third parties.

Development of the draft ISPM

- [3] The need for the development of an ISPM was recognized from two perspectives:
- to provide guidance to NPPOs on the management of authorization by ensuring the entity is properly authorized and appropriately overseen by the authorizing NPPO
 - to use this guidance as assurance, to foster trust among NPPOs when specific phytosanitary actions are performed by other entities.
- [4] The topic for the development of an ISPM on *Authorization of non-NPPO entities to perform phytosanitary actions* (2014-002) was recommended to the standard setting work programme in 2013 by the Standards Committee (SC), and added by the Commission of Phytosanitary Measures (CPM) at their 9th meeting (CPM-9) in 2014. The Specification was submitted for consultation in 2014 and modified based on comments of CPs. The SC approved Specification 65 (Authorization of entities to perform phytosanitary actions) at their May 2016 meeting. An expert working group convened in 2017 and drafted the ISPM, which was reviewed and approved for consultation in 2018 by the SC.

First Consultation: Concerns and associated discussions

- [5] During the 2018 consultation period, 977 comments were submitted. Significant concerns were expressed by some contracting parties (CPs) that quarantine phytosanitary control is a public function that serves to preserve the phytosanitary security of a country. The delegation of phytosanitary actions to private entities is considered to endanger this phytosanitary security. The delegation of authority is also feared to weaken the position of the NPPO and the relevance of its work. The concerns were discussed by the Strategic Planning Group (SPG) in October 2018 and the CPM in April 2019. Legal opinion was also sought on delegation of authority under the context of Article V2(a).

Strategic Framework 2020-2030

- [6] The SPG 2018 discussed the issue from the perspective of the Strategic Framework 2020-2030 under the Development Agenda, “Developing Guidance on the Use of Third Party Entities”. The SPG decided that the section on third party entities would be rewritten to clarify that the IPPC is not promoting authorization, but is only providing guidance to improve quality and harmonize actions in cases when NPPOs decide to authorize third parties.

Commission on Phytosanitary Measures

- [7] CPM-14 (2019) discussed the concerns on the draft ISPM under the agenda on conceptual challenges in standards development in terms of implementation. Some CPs did not support the development of the draft standard, while several CPs expressed support for its development. They considered the standard necessary as it provided guidance to NPPO's, particularly in light of the increased practice of countries already using authorization, increased volume of trade and the often limited resources of the NPPO, while maintaining phytosanitary security.
- [8] The FAO Legal Division confirmed that Article V.2 (a) of the IPPC provides the possibility to NPPOs to authorize entities to perform phytosanitary actions with the exception of the issuance of phytosanitary certificates, and indicated that the responsibility for the phytosanitary action remained with the NPPO. FAO Legal also confirmed that activities such as auditing can be authorized.
- [9] The draft standard makes it clear that authorization is not mandatory and gives guidance for NPPOs who have decided to authorize entities. Legal advice has been sought and heeded, pointing out that implementation of ISPMs is not mandatory but that ISPMs provide guidance to promote harmonization

Second Consultation: Outstanding concerns

- [10] SC May 2019 and SC working group (SC-7) further discussed and made major revisions to the draft ISPM, which clearly stated that there is no obligation for NPPOs to authorize entities to perform phytosanitary actions. The SC and SC-7 recognized that the concept of third-party entities performing NPPO functions is very sensitive for some CPs and ensured care was taken in the precise wording of the standard, especially the headings, so that it is clear that the standard is neither mandating, encouraging or endorsing authorization but merely providing guidance to support those NPPOs that wish to or need to authorize third-party entities. The responsibility for NPPO functions and authorized activities would always remain with the NPPO.
- [11] The draft was approved for Second Consultation. During the Second Consultation, 515 comments were received and some significant concerns were identified. The SC resolved two of the three significant concerns and modified the text of the draft ISPM accordingly. The concerns are:
- **Comments not supporting further work on the draft ISPM.** Six comments had not supported further work on the draft ISPM. These expressed concerns over the following issues: national legal frameworks currently in existence not providing for the possibility of empowerment of entities other than the NPPO to perform the phytosanitary activities listed in the draft standard; the reliability of phytosanitary certificates issued as a result of a process involving such entities; the need for NPPO functions to be regulated at the national level; and authorization of entities to perform phytosanitary actions not being a phytosanitary measure. It was also indicated that the IPPC considers the possibility of authorizing entities to perform phytosanitary actions only in cases where the NPPO is not in a position to perform such functions itself. According to the comments, the adoption of an international standard on this topic would set a precedent and would allow the delegation of authority to be considered as a normal situation.
 - **ISPM needing further development and deletion of the section on “Roles and responsibilities of entities authorized to audit or supervise”.** Two of the comments had said that the draft ISPM is not yet ready for presentation to CPM for adoption and recommended that

the development of the draft ISPM be aligned with that for the draft ISPM on *Audit in the phytosanitary context* (2015-014). It was also proposed to delete the section on “Roles and responsibilities of entities authorized to audit or supervise” (either because this will be dealt with by the draft standard on *Audit in the phytosanitary context* (2015-014) or because, according to the comments, audit and supervision are not phytosanitary actions), and requested to clarify the meaning of audit and of supervision.

Resolved by SC: The SC, in its May 2019 meeting, agreed that the section on auditing should be retained in the draft standard, as it does not go into detail and only relates to the authorization aspects of auditing, so it would not overlap with the new draft ISPM to be developed on *Audit in the phytosanitary context* (2015-014). The SC also agreed that audit is a phytosanitary action as per ISPM 5. The Steward recalled that the TPG had not seen the need to define audit and supervision and had suggested using the dictionary meaning, and that the SC-7 had subsequently recommended defining the terms in the draft ISPM on *Audit in the phytosanitary context* (2015-014). The SC amended this section to make it clear that it is not an obligation for the NPPO to grant authorization to an entity to conduct audit.

- **Free of conflict of interest vs manage conflict of interest.** Nine comments had related to whether entities should be free of conflicts of interest (seven comments) or whether conflicts of interest should be managed (two comments). The Steward noted a consultation comment that managing conflicts of interest contradicts with section 3.1 of ISPM 7 (*Phytosanitary certification system*), which says that non-NPPO personnel should be subject to restrictions and obligations equivalent to those for government officials and have no conflicts of interest.

Resolved by SC: The Steward suggested that the standard could say that the NPPO should set the framework for conflicts of interest, which would then leave it to the discretion of the NPPO as to whether entities need to be free from conflicts of interest or can have managed conflicts of interest. After further discussion, the SC inserted some text in the section on “Development of authorization programme” and in the section on “Criteria for eligibility of entities” to say that NPPOs should develop a framework to assess and identify potential conflicts of interest and address them appropriately, and that to be eligible the entity needs to conform with the requirements of the NPPO on conflicts of interest.

Concerns regarding the concept of authorization

- [12] The SC had a wide-ranging discussion over whether the text of the draft standard should be submitted for adoption, recognizing both the concerns expressed by some CPs about the implementation of this standard and the care and attention that the SC has already devoted to addressing these concerns.
- [13] It was noted that the concerns expressed by some regions were not about technical issues with the standard but related to mistrust in the concept of authorization. Concerns cited included perceived mistrust between NPPOs and the private sector in terms of whether such entities would adequately discharge their duties and that authorization could potentially undermine the functions of NPPOs. Another concern for some countries was that implementing this standard at this time might undermine their ability to progress with implementing fundamental trade facilitation agreements.
- [14] In response to these concerns from CPs, the SC noted that:
- Many countries authorize entities when implementing ISPM 15, so the concept has already been accepted and is also highlighted in several adopted ISPMs. The Steward commented that the issues raised during both rounds of consultation have been addressed in the text of the draft standard, so there is not much more that can be done to the text to address concerns about the concept.

- When objections are submitted at CPM, they need to be technically justified, so any objection would need to relate to technical issues with the standard. The standard setting procedure, amended by CPM in 2016, indicates that an objection must be accompanied by technical justification and suggestions for improvement of the draft ISPM which are likely to be acceptable to other CPs. In the current situation with the draft ISPM on authorization, the objection to the adoption of the ISPM is not related to the technical content or requirements of the ISPM, but it is related to the acceptance of the concept of authorization.

- [15] One SC member commented that although their country had initially had reservations about the authorization of entities, they do now authorize entities and they have memoranda of understanding to control the activities of these entities. In their view, developing countries may benefit from the standard as authorization of entities can provide access to skills and infrastructure additional to those of the NPPO.
- [16] The IFU lead informed the SC that work is being undertaken within the framework of the IRSS to conduct a desk study on the application of the concept of the authorization of entities. This should provide examples of where and authorization has been used as well as outline some of the complexities that may determine whether or not an authorization programme can meet its intended outcome. It is hoped that this study will be done in early 2020 and thus in time for CPM-15 (2020).
- [17] The Steward expressed his concern that if the draft standard on authorization is postponed because the basic concept is not yet accepted, then this would bring into question the Standard setting process itself, as the draft standard has been developed based on a topic approved by CPM and a detailed specification that underwent consultation, and furthermore the draft ISPM has been reviewed by the SC and has been through two country consultations. He also recalled that authorization of entities is specifically mentioned in several adopted ISPMs and the development agenda of the new Strategic Framework 2020-2030. Another SC member expressed the view that it would be setting a precedent if a decision of the SC is determined by issues that are not technical.

Seeking guidance and direction from CPM

- [18] The concerns about this draft standard are not of a technical nature, and thus the resolution of these concerns is a matter for CPM rather than the SC. Therefore, the SC continued to work on the text to take account of the second consultation comments, present this revised draft to CPM-15 (2020) (Appendix 1) with an explanation of the concerns expressed by some NPPOs, and leave it to CPM-15 (2020) to decide whether to have a vote to adopt it or to ask the SC to work on it further.

Recommendations

- [19] The CPM is invited to:
- (1) *discuss* the above concerns and *decide* on the path forward for the draft ISPM on *Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions* (2014-002) (Appendix 1).

Small Working Group Members:

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Appendix 1 – Draft ISPM on *Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions* (2014-002)

DRAFT ISPM: REQUIREMENTS FOR NATIONAL PLANT PROTECTION ORGANIZATIONS IF AUTHORIZING ENTITIES TO PERFORM PHYTOSANITARY ACTIONS (2014-002)

Status box

This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
Date of this document	2019-12-02
Document category	Draft ISPM
Current document stage	To CPM-15 (2020)
Major stages	<p>2013-11 Standards Committee (SC) recommended topic <i>Authorization of non-NPPO entities to perform phytosanitary actions</i> to be added to the work programme.</p> <p>2014-04 CPM-9 added the topic <i>Authorization of non-NPPO entities to perform phytosanitary actions</i> (2014-002) to the work programme with priority 3 (subsequently changed to priority 2 by CPM-10).</p> <p>2016-05 SC approved Specification 65 (<i>Authorization of entities to perform phytosanitary actions</i>).</p> <p>2017-06 Expert working group drafted ISPM.</p> <p>2018-05 SC revised and approved draft for first consultation.</p> <p>2018-07 First consultation.</p> <p>2019-05 SC-7 revised and approved draft for second consultation.</p> <p>2019-07 Second consultation.</p> <p>2019-11 SC revised the draft.</p>
Steward history	<p>2016-05 SC Mr Rajesh RAMARATHNAM (CA, Lead Steward)</p> <p>2016-05 SC Ms Marina ZLOTINA (US, Assistant Steward)</p> <p>2014-05 SC Ms Marie-Claude FOREST (CA, Lead Steward)</p>
Notes	<p>2017-09 Edited</p> <p>2018-05 Edited</p> <p>2019-05 SC-7 changed title to <i>Requirements for NPPOs if authorizing entities to perform phytosanitary actions</i></p> <p>2019-05 Edited</p> <p>2019-12 Edited</p>

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Adoption

[To be inserted following adoption]

INTRODUCTION

Scope

- [1] This standard provides requirements for national plant protection organizations (NPPOs) if they decide to authorize entities to perform specific phytosanitary actions on their behalf.
- [2] In accordance with Article V.2(a) of the IPPC, this standard does not cover the issuance of phytosanitary certificates. Also, this standard does not cover the development and establishment of phytosanitary measures.

References

- [3] The present standard refers to ISPMs. ISPMs are available on the International Phytosanitary Portal (IPP) at <https://www.ippc.int/core-activities/standards-setting/ispms>.

IPPC. 1997. *International Plant Protection Convention*. Rome, IPPC Secretariat, FAO.

Definitions

- [4] Definitions of phytosanitary terms used in this standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

Outline of Requirements

- [5] This standard outlines the key requirements for the development of an authorization programme and the eligibility criteria for entities to become authorized. The standard identifies the roles and responsibilities of the parties involved in the implementation of an authorization programme. It also describes processes for audits, types of nonconformities, and suspension and revocation of authorization.

BACKGROUND

- [6] Article IV of the IPPC sets out the responsibilities for NPPOs. Article V.2(a) of the IPPC provides for the possibility of NPPOs authorizing entities to perform phytosanitary actions. The concept of authorization is referred to in several ISPMs, such as ISPM 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*), ISPM 6 (*Surveillance*), ISPM 7 (*Phytosanitary certification system*), ISPM 12 (*Phytosanitary certificates*), ISPM 20 (*Guidelines for a phytosanitary import regulatory system*), ISPM 23 (*Guidelines for inspection*), ISPM 42 (*Requirements for the use of temperature treatments as phytosanitary measures*) and ISPM 43 (*Requirements for the use of fumigation as a phytosanitary measure*). In order to foster confidence between NPPOs, there is a need to harmonize the requirements for authorizations of specific phytosanitary actions and to ensure that the practice aligns with the principles of the IPPC. If an NPPO decides to authorize entities, it remains responsible for the phytosanitary actions performed by the entities on its behalf.

IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

- [7] Authorization programmes may have a positive impact on biodiversity and the environment because they may contribute to the delivery of phytosanitary actions.

REQUIREMENTS

[8] There is no obligation for NPPOs to authorize entities to perform phytosanitary actions. However, if an NPPO decides to authorize entities, the following requirements apply.

1. Basic Understanding of Authorization

[9] An NPPO decides whether to use authorization of entities to perform phytosanitary actions. Authorization may be used by NPPOs to authorize entities to perform specific phytosanitary actions, to audit other authorized entities, or to supervise phytosanitary actions. Examples of phytosanitary actions that an NPPO may decide to authorize an entity to perform include monitoring, sampling, inspection, testing, surveillance, treatment, post-entry quarantine and destruction. If an NPPO decides to authorize entities, it should have sole responsibility for deciding which entity is authorized and for which specific phytosanitary actions. Audits may be conducted by an authorized entity in order to assess the eligibility of another entity to perform a specific phytosanitary action; however, the decision to authorize should be the responsibility of the NPPO alone.

[10] The NPPO is responsible for ensuring that the authorized entity performs the phytosanitary actions according to the NPPO's requirements. With the authorization, the phytosanitary action is performed by the entity but the responsibility remains with the NPPO. Authorization may be given only to perform phytosanitary actions to implement phytosanitary measures that are decided by the NPPO. Authorization to perform phytosanitary actions does not include NPPO core activities such as issuance of phytosanitary certificates or development and establishment of phytosanitary measures because these are not phytosanitary actions. The NPPO should have sufficient staff with the necessary expertise to carry out oversight, including auditing, of authorized entities.

[11] In this standard, "entities" include the providers of phytosanitary action (e.g. individuals, organizations, enterprises) and, where appropriate, their facilities (such as equipment, laboratories, treatment enclosures). In some cases, authorization of entities may require an NPPO to approve individuals within the entity (such as those responsible for specific phytosanitary actions), relevant documentation, facilities, or any combination of these. The NPPO and the entity should determine the nature of the authorization agreement.

2. Authorization programme

[12] Under its phytosanitary system, an NPPO deciding to authorize entities to perform specific phytosanitary actions should establish an authorization programme.

[13] Before deciding to authorize entities to perform phytosanitary actions and developing an authorization programme, NPPOs should ensure that their country's legal framework enables them to authorize, suspend, revoke and reinstate authorizations.

[14] NPPOs should only set up authorization programmes that result in effective phytosanitary actions that are delivered with integrity and transparency. The authorization programme should ensure that the authorized entities are accountable to the NPPO for these actions and that phytosanitary security is maintained, consistent with the provisions of the IPPC and ISPMs.

2.1 Development of Authorization Programme

The NPPO should develop an authorization programme that is appropriate for its purposes, first defining the programme's scope and objectives. When developing an authorization programme, the NPPO should:

- set the requirements that must be met by an entity to be authorized
- develop procedures for receiving, maintaining and delivering information, including procedures to ensure confidentiality
- develop procedures to process the information received, from the time of receipt of the information required by the NPPO and its subsequent evaluation to the decision on whether to grant authorization to the entity

- develop a training plan to ensure that NPPO personnel have the expertise to manage the authorization programme
- develop training or identify minimum training, equipment, competency and skills requirements for entities to perform phytosanitary actions; these requirements should be equivalent to those required for the NPPO if it were to undertake the same phytosanitary actions
- develop a template agreement that can be used to formalize the authorization of entities and make the authorization legally binding
- determine a validity period for the authorization agreement, including the timing of any review and the length of any extension if appropriate
- develop specific performance criteria, guidelines and performance-based verification processes for the actions performed by the entities
- develop an audit or monitoring process and supporting tools, which may include audit or monitoring checklists and templates for audit or monitoring reports, and templates for corrective action reports
- develop criteria to determine nonconformities
- develop a process to address nonconformity, this including, where appropriate, suspending, reinstating or revoking authorization
- develop a process for the authorized entity to voluntarily withdraw from the authorization agreement with the NPPO
- identify risks which may arise from authorization and which need to be managed through the authorization programme
- develop contingency plans for ensuring continuity of action in the event that an authorized entity has its authorization suspended or revoked or voluntarily withdraws from the authorization programme
- develop a process to ensure efficient and effective communication between the NPPO and the authorized entity
- develop a process to maintain an up-to-date list of authorized entities.
- develop a framework to assess the impartiality and independence of entities, and to assess and identify any potential conflicts of interest and address them appropriately (e.g. by requiring entities to be free of any conflict of interest or by allowing entities to manage conflicts of interest).

3. Criteria for Eligibility of Entities

The NPPO should ensure that the entity meets the following criteria:

- it can legally operate in the country of authorization
- it has the ability to enter into an agreement with the NPPO
- it has sufficient resources (financial and human), including the expertise, equipment and infrastructure required, to undertake the specific phytosanitary actions to be performed and to ensure continuity of service
- it appoints or identifies the individual or individuals who will be responsible for delivery of the phytosanitary actions to be performed
- it has documentation demonstrating the process by which it will consistently meet the requirements set by the NPPO for the phytosanitary actions to be performed
- it agrees to conform with the NPPO's requirements, including requirements on impartiality, independence and conflicts of interest (e.g. to declare whether it is free of any conflict of interest or to identify potential conflicts of interest)
- it has a clear statement of liability for damages if these result from actions it performs in its role as an authorized entity

- it has a process to ensure efficient and effective resolution of conflicts with the client receiving delivery of the phytosanitary action (if the client is not the NPPO), including a process to elevate issues to the NPPO for a final decision.

4. Roles and Responsibilities for Implementing the Authorization Programme

4.1 Roles and responsibilities of the NPPO

The roles and responsibilities of the NPPO should include the following:

- to assess the entity against the criteria for eligibility for authorization set in this standard and those established by the NPPO
- to evaluate the entity against the requirements set by the NPPO regarding its documented procedures and their implementation on-site, and propose suggestions for improvement as necessary
- to clearly define the phytosanitary actions the entity is authorized to perform and the performance criteria
- to enter into an agreement which authorizes the entity to perform specific phytosanitary actions, and to review and update the agreement as necessary
- to notify entities that do not meet the criteria for eligibility and provide the rationale for the decision
- to train NPPO personnel and, if needed, authorized entities' personnel and ensure that their skills and competencies are maintained at an adequate level to consistently implement the authorization programme
- to carry out regular audits or monitoring of the authorized entity to verify that it conforms with the requirements of the NPPO's authorization programme
- to carry out internal audits of its own procedures and processes to verify that the objectives of its authorization programme continue to be met
- to implement processes for addressing identified nonconformities, including determining the corrective actions and requiring the authorized entity to take the corrective actions, and, where appropriate, suspending or revoking authorization, which may include regulatory enforcement
- to implement processes for reinstatement of authorization
- to implement processes for the entity to voluntarily withdraw from the authorization agreement with the NPPO, when needed
- to maintain documentation, including records and published lists of authorized entities, corresponding authorized phytosanitary action, and authorization period, if applicable
- to identify for how long an entity needs to save its records, in relation to the specific phytosanitary actions performed
- to implement and maintain transparent, efficient and effective communication on the authorization programme, in particular between the NPPO and the authorized entities
- to ensure that NPPO personnel involved in authorization of entities maintain impartiality and are free of any conflict of interest.

4.2 Roles and responsibilities of the entity

The roles and responsibilities of the entity should include the following:

- to provide required information to the NPPO when being considered for authorization to perform specific phytosanitary actions
- to enter into a written agreement to perform the specific phytosanitary actions
- to implement documented procedures to conform with the requirements set by the NPPO, which may cover:

- operating procedures describing how specific phytosanitary actions are performed (i.e. who does what, when, where and how)
- skills and competency of personnel
- training of personnel
- document control, which includes:
 - revision of documents
 - records, in particular of the activities undertaken in relation to the specific phytosanitary actions
- a list of equipment and their maintenance or calibration schedule, where appropriate
- internal audit
- management of nonconformity
- to provide notification (within an agreed time frame) to the NPPO upon a major change in management or location, a change in process, a nonconformity or any other information that has an impact on the specific phytosanitary action that has been authorized
- to maintain infrastructure and security, where applicable, and resources to consistently carry out the specific phytosanitary actions to conform with the requirements set by the NPPO
- to ensure that personnel have the relevant knowledge and experience required by the NPPO to perform the specific phytosanitary actions
- to train personnel and ensure that their skills and competencies are maintained at an adequate level to consistently carry out the specific phytosanitary actions to conform with the requirements set by the NPPO
- to maintain and provide documented procedures (including records of its activities) to the NPPO as required
- to undergo monitoring, audits and controls as described in the requirements set by the NPPO
- to comply with the requirements set in the authorization agreement, the phytosanitary procedures, standards, legislation and guidelines of the NPPO that relate to the authorization
- to maintain the confidentiality of the information obtained through the authorized phytosanitary actions.

4.2.1 Roles and responsibilities of entities authorized to audit or supervise

The NPPO may choose to authorize entities to audit other authorized entities or to supervise phytosanitary actions. An entity that audits other authorized entities or supervises phytosanitary actions should meet the requirements in section 4.2. The roles and responsibilities of the entity should also include the following:

- to develop and carry out an action plan, including procedures or corrective actions, for dealing with nonconformities of the entities it audits that compromise the integrity of and trust in the programme, including notification (within an agreed time frame) of these to the authorizing NPPO
- to maintain confidentiality of information gained through its auditing or supervisory activities
- to maintain impartiality and independence from the entities it audits or supervises, and be free of any conflict of interest
- to ensure personnel have the relevant knowledge, experience and training to carry out the specific audits or supervision being performed
- to undertake internal audits to provide continuous feedback and identify system gaps (if applicable).

5. Process for Audits

5.1 Audits to authorize an entity

- [15] If an NPPO decides to consider the authorization of an entity, the NPPO (or the entity authorized to conduct audits) should first carry out an initial evaluation of the entity's documented procedures.
- [16] When the documented procedures are acceptable, the NPPO (or the entity authorized to conduct audits) should carry out an audit to evaluate the entire system and the capability of the entity to implement the documented operating procedures for each phytosanitary action.
- [17] At each step of the audit, the NPPO (or the entity authorized to conduct audits) should provide feedback to the entity on observations and opportunities for improvement as necessary.
- [18] The decision about whether to grant authorization should rest solely with the NPPO. The NPPO should only authorize the entity if the audit demonstrates that the NPPO's requirements for authorization of entities have been met.

5.2 Audits to maintain authorization

- [19] The NPPO should determine the minimum frequency of the audits to maintain authorization, based on the scope and complexity of the phytosanitary actions and the associated level of pest risk, the performance of the authorized entity and the nonconformities identified, and the results of previous audits. An unscheduled audit may be conducted, for instance upon receipt of a notification of non-compliance from an importing country.
- [20] Audits may be conducted by the NPPO (or the entity authorized to conduct audits) on a specific part or parts of the entity's system, as necessary.

6. Types of Nonconformity

- [21] When the authorized entity does not meet the requirements specified by the NPPO as set out in the authorization agreement, this should be considered as a nonconformity.
- [22] A nonconformity may be identified during audits, supervision, or investigations triggered by notification of non-compliance (ISPM 13 (*Guidelines for the notification of non-compliance and emergency action*)).
- [23] The type and number of nonconformities identified should be used by the NPPO to determine the status of the entity (authorized, suspended or revoked) and the follow-up audit frequency.
- [24] If a nonconformity is identified, the NPPO (or the entity authorized to audit or supervise) should require the authorized entity to take corrective action.
- [25] Nonconformities may be considered as critical nonconformities (section 6.1) or other nonconformities (section 6.2).

6.1 Critical nonconformity

“Critical nonconformity” is a nonconformity that immediately impacts the integrity of and trust in the NPPO's phytosanitary system and that requires a rapid corrective action to be identified and implemented. The NPPO may consider nonconformities to be critical in situations such as:

- when there is evidence of failing to properly perform authorized phytosanitary actions
- when a corrective action is not implemented to the satisfaction of the NPPO (or the entity authorized to audit or supervise)
- when there is a failure to implement timely corrective actions to remedy the shortcomings identified
- when the integrity or impartiality of the entity is shown to have been compromised
- when there is evidence of fraud.

[26] An entity's authorization to perform a specific phytosanitary action should be suspended or revoked immediately if a critical nonconformity is identified. The NPPO should have a system in place to manage the critical nonconformity.

6.2 Other nonconformity

[27] "Other nonconformity" is a nonconformity that does not directly or immediately impact the integrity of and trust in the NPPO's phytosanitary system and is not considered a critical nonconformity by the NPPO.

[28] Other nonconformity requires corrective actions to be taken within a time frame specified by the NPPO (or the entity authorized to audit or supervise).

[29] Suspension or revocation of the authorization is not needed but may be considered when this type of nonconformity is repeatedly identified or when corrective actions are not taken within the required time frame. The decision about whether to suspend or revoke authorization of the entity should rest solely with the NPPO.

7. Suspension and Revocation of Authorization

[30] The decision to suspend, revoke or reinstate authorization of the entity should rest solely with the NPPO.

[31] **Suspension.** The NPPO temporarily suspends the authorization of an entity for a specified time in order for the entity to implement corrective action.

[32] **Revocation.** The NPPO withdraws the authorization of an entity.

[33] An entity that has had its authorization suspended and that wishes to have its authorization reinstated should apply to the NPPO for reinstatement. When an entity's authorization has been revoked, the NPPO should evaluate if the entity is eligible for a new authorization. Affected entities should make an application for a new authorization, according to the rules set by the NPPO. The decision about whether to reinstate an entity's authorization should rest solely with the NPPO.

[34] An entity that has voluntarily withdrawn from an authorization agreement and that wishes to have its authorization reinstated should apply to the NPPO for reinstatement.